

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ROY WILMOTH, JR., *et al.*,

Plaintiffs,

v.

ALEX AZAR, in his capacity as Secretary of
the United States Department of Health and
Human Services,

Defendant.

Case No. 1:19-cv-03556

**PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
ITS MOTION FOR SUMMARY JUDGEMENT**

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Pursuant to FED. R. CIV. P. 56 and LCvR 56(h)(2), (n), Plaintiffs, Medicare beneficiaries Roy Wilmoth, Jr., Maureen Piekanski, and Edwin R. Banks (collectively, “Plaintiffs”) respectfully submit this motion for summary judgment in this consolidated administrative appeal of adverse Medicare coverage decisions.

As detailed in the Complaint and in this memorandum, each of the Plaintiffs is suffering from a deadly form of brain cancer, glioblastoma multiforme, or GBM. Each Plaintiff is seeking to appeal an adverse coverage decision for critical, life-prolonging medical treatment, tumor treatment field therapy (“TTFT”). In a particularly cruel and arbitrary manner, after repeatedly recognizing that the TTFT is medically reasonable and necessary treatment that is covered under Medicare, the Secretary changed course and began arbitrarily denying coverage, requiring Plaintiffs, on a month-to-month basis, to repeatedly seek to establish that they are entitled to coverage of this critical treatment.

This administrative appeal presents a narrow and important question of administrative law arising from the Secretary’s denial of Medicare coverage to the Plaintiffs for this critical medical device. As a matter of law, the Secretary should be bound by the Supreme Court’s decision in *Astoria Federal Savings & Loan v. Solimino*, 501 U.S. 104 (1991), such that collateral estoppel can apply against the Secretary where the Secretary has previously litigated, and lost, an issue against the same party.

As set forth herein, the Secretary is barred by collateral estoppel from re-litigating the issue, and Plaintiffs are entitled to judgment as a matter of law. In addition, notwithstanding the prior decisions, the Secretary’s decisions denying coverage for TTFT are arbitrary and capricious as inconsistent with applicable law. Under either rationale, the Court should grant summary judgment in favor of Plaintiffs, finding that TTFT is a Medicare covered benefit and that it is

medically reasonable and necessary and remand this case with instructions to effectuate the Court's decision.

I. LEGAL BACKGROUND

A. Motions for Summary Judgment

Pursuant to FED. R. CIV. P. 56(b), absent a local rule or court order otherwise, a motion for summary judgment may be filed "at any time." As indicated in the Advisory Committee Notes to both the 2009 and 2010 amendments, "any time" includes the commencement of the case. Indeed, courts in this district have noted that in Administrative Procedure Act cases "early summary judgment motions are often appropriate." *See American Hospital Assoc. v. HHS*, 2018 WL 577397 (D.D.C. Nov. 2, 2018) (Bates, J.) (motion for summary judgment filed concurrently with Complaint appropriate, especially in APA cases).

B. Collateral Estoppel

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. For collateral estoppel to apply, three conditions must be met. First, the issue must have been actually litigated in the prior proceeding – *i.e.*, "contested by the parties and submitted for determination by the Court." *See, e.g., Mexichem Fluor, Inc. v. E.P.A.*, 780 Fed. App'x 6 (D.C. Cir. 2019) (*citing Jack Faucett Assoc., Inc. v. A.T. & T. Co.*, 744 F.2d 118, 124 (D.C. Cir. 1984)). Second, it must have been actually and necessarily determined by a court of competent jurisdiction in the prior case. Third, preclusion "must not work an unfairness." *Id.* Presumed in these tests is that the prior decision is a final decision. Further, some courts list an additional requirement that there must have been a full and fair opportunity to litigate the issue on which collateral estoppel is asserted. *See, e.g., Montana v. U.S.*, 440 U.S. 147, 153-4 (1979).

Parallel/concurrent litigation is common, especially federal/state litigation. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]”). Thus, a later filed case that reaches finality first may have preclusive effect on an earlier filed, but still on-going litigation.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015). The application of collateral estoppel to agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App'x. 542 (6th Cir. 2005) (SSA administrative law judge (ALJ) collaterally estopped by prior

ALJ' work determination); *Islam v. U.S. D.H.S.*, 136 F.Supp.3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge' determination).

C. Arbitrary and Capricious

In *Independent Petroleum Ass'n of Am. V. Babbitt*, 92 F.3d 1248, 1258, 1260 (D.C. Cir. 1996) the Court of Appeals held:

An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.

* * *

The treatment of cases A and B where the two cases are functionally indistinguishable, must be consistent. That is the very meaning of the arbitrary and capricious standard.

Numerous courts in this district have upheld/relied on this proposition. *See, e.g., Etelson v. Office of Pers. Mgmt.*, 684 F.2d 918, 926 (D.C. Cir. 1982) ("Government is at its most arbitrary when it treats similarly situation people differently."); *Doubleday Board. Co. v. FCC*, 655 F.2d 417, 423 (D.C. Cir. 1981) (arbitrary and capricious to "decide a case one way today and a substantially similar case another way tomorrow without a reasonable explanation"); *Plunkett v. Castro*, 67 F. Supp. 3d 1, 21-2 (D.D.C. 2014); *El Rio Santa Cruz Neighborhood Health Center, Inc. v. H.H.S.*, 300 F. Supp. 2d 32, 42-3 (D.D.C. 2004); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 27-9 (D.D.C. 1997) ("If an agency treats similarly situated parties differently, its action is arbitrary and capricious in violation of the APA.") (internal quotations and citations omitted);

II. FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. Even with traditional forms of treatment, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.¹

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)² in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.³

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT saves and/or extends GBM patients' lives, in some cases, by years. Between

¹ In much scientific research, study participants are randomly assigned to "control" and "test" groups. The "control" group does not receive the treatment being tested. In contrast, the "test" group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the "test" group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the "control" group. In those circumstances, withholding the treatment from the "control" group would be unethical.

² The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journal in the United States and the world.

³ See *Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Thus, after a patient is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will continue that treatment for the rest of their hopefully extended lives.

B. The Medicare Appeals Process

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request “redetermination.” If the claim is still denied, the beneficiary can request “reconsideration.” If the claim is still denied, the beneficiary can appeal to an administrative law judge (ALJ). The Secretary may choose to participate in the hearing held by the ALJ. Alternatively, the Secretary may choose not to participate in the ALJ hearing and rely on the fact that the Medicare beneficiary bears the burden of establishing coverage. If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council (“Council”). Finally, if the claim is still denied, the beneficiary can file suit in district court.

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. Thus, Medicare beneficiaries seeking

coverage are often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

C. Facts Specific to Mr. Wilmoth

Mr. Wilmoth is a 71-year-old retired telephone company employee, father of two (2) and grandfather to five (5). Along with his wife of nearly forty (40) years (Paulette), Mr. Wilmoth lives in Mississippi - just outside of Memphis, Tennessee. In his free time, Mr. Wilmoth enjoys restoring old cars and fishing. Mr. Wilmoth was diagnosed with a GBM in February 2016 and, after surgery and chemo-radiation, Mr. Wilmoth began receiving TTFT in May 2017.

D. Favorable Decisions That Have Become Final⁴

a. Appeal No. 1-7835293187

On December 13, 2018, ALJ Lissette Figueroa issued a decision in Appeal No. 1-7835293187 on claims related to the months of October, November, and December 2017 finding that Medicare coverage was appropriate for Mr. Wilmoth. Among other findings, Judge Figueroa found that TTFT treatment was safe and effective and medically reasonable and necessary for Mr. Wilmoth. *See* Declaration of James C. Pistorino (“Pistorino Decl.”) ¶ 4, Ex. A at 12 (“[Mr. Wilmoth’s] use of the Optune device, HCPCS Code E0766, during dates of service meets requirements for Medicare Part B DME coverage because the device is shown to meet the definition of durable medical equipment, to have been reasonable and necessary for the treatment of [Mr. Wilmoth’s] GBM, and to have been for use in [Mr. Wilmoth’s] home.”). Thus, Judge

⁴ In addition to the decision listed below, on October 17, 2019, ALJ Carolyn Cohn-Morros issued a decision Appeal No. 1-8736200501 on claims related to the months of January, February, and March 2019. Pistorino Decl. ¶ 10, Ex. G. As with the other decisions listed, Judge Cohn-Morros found that TTFT was safe and effective and medically reasonable and necessary for Mr. Wilmoth. Accordingly, Judge Cohn-Morros found that coverage should be allowed and ordered coverage. If the Secretary does not appeal, this decision will become final on December 17, 2019.

Figueroa ordered coverage of Mr. Wilmoth's claims. The Secretary chose not to participate in the hearing conducted by Judge Figueroa or to submit briefs. The Secretary did not appeal Judge Figueroa's decision and the decision became final on February 13, 2019.

b. Appeal No. 1-8236683474

On April 25, 2019, ALJ Andrew Henningfeld issued a decision in Appeal No. 1-8236683474 on claims related to the months of January, February, and March 2018 finding that coverage was appropriate for Mr. Wilmoth. Among other findings, Judge Henningfeld found that TTFT treatment was medically reasonable and necessary for Mr. Wilmoth and a covered Medicare benefit. *See* Pistorino Decl. ¶ 6, Ex. C at 6 ("The record shows the DMEPOS at issue does satisfy the applicable Medicare coverage criteria. The DMEPOS at issue was reasonable and necessary. It is therefore covered under Medicare Part B."). Thus, Judge Henningfeld ordered coverage of Mr. Wilmoth's claims. The Secretary chose not to participate in the hearing conducted by Judge Henningfeld or to submit briefs. The Secretary did not appeal Judge Henningfeld's decision and the decision became final on June 25, 2019.

c. Appeal No. 1-8415320334

On July 2, 2019, ALJ Joseph Petrylak issued a decision in Appeal No. 1-8415320334 on claims related to the months of July, August, and September 2018 finding that coverage was appropriate for Mr. Wilmoth. Among other findings, Judge Petrylak found that TTFT was the standard of care for treating GBM, that it was very effective, and that coverage criteria had been met. *See* Pistorino Decl. ¶ 9, Ex. F at 5 ("Accordingly, coverage criteria have been met[.]"). Thus, Judge Petrylak ordered coverage of Mr. Wilmoth's claims. The Secretary chose not to participate in the hearing conducted by Judge Petrylak or to submit briefs. The Secretary did not appeal Judge Petrylak's decision and the decision became final on September 2, 2019.

2. The Decision At Issue In This Case

On May 7, 2019, ALJ Kenneth Bryant issued a decision in Appeal No. 1-8363484331 on claims related to the months of April, May, and June 2018. Contrary to the decision, *e.g.*, of ALJ Figueroa (which he had before him), ALJ Bryant held that TTFT treatment for Mr. Wilmoth “was not medically reasonable and necessary” and, therefore, was not a covered benefit. *See* Pistorino Decl. ¶ 7, Ex. D at 7.

Mr. Wilmoth timely appealed. In particular, Mr. Wilmoth noted the prior decisions from ALJs Figueroa, Petrylak, and Henningfeld finding Medicare coverage appropriate. As a result, Mr. Wilmoth argued that the Secretary was collaterally estopped from re-litigating that issue.

In a decision issued on October 15, 2019, the Council held that, because its regulations (42 C.F.R. § 405.1108(a)) indicate that Council review is *de novo*, collateral estoppel does not apply. Thus, the Council denied Mr. Wilmoth’s claim for coverage.

E. Facts Specific to Mrs. Piekanski

Mrs. Piekanski is a 64 year-old retired grocery store employee, mother/step-mother of four (4), and grandmother to ten (10). Along with her husband of more than 20 years (Theodore), Mrs. Piekanski currently lives in Throop, Pennsylvania – just outside Scranton. In her free time, Mrs. Piekanski enjoys music and spending time with her family.

Mrs. Piekanski was diagnosed with GBM in 2011 and, after surgery and chemo-radiation, Mrs. Piekanski began using the Optune device in August 2011.

1. Favorable Decisions That Have Become Final

a. Appeal No. 1-7835229465

On November 7, 2018, ALJ Jeffrey Gulin issued a decision in Appeal No. 1-7835229465 on claims related to the months of September, October, and November 2018 finding that coverage was appropriate for Mrs. Piekanski. Among other findings, Judge Gulin found that TTFT

treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. *See* Pistorino Decl. ¶ 11, Ex. H at 6 (“The service was medically reasonable and necessary as required by Section 1862(a)(1)(A) of the Act and the Applicant is entitled to Medicare coverage.”). Thus, Judge Gulin ordered coverage of Mrs. Piekanski’s claims. The Secretary chose not to participate in the hearing conducted by Judge Gulin or to submit briefs. The Secretary did not appeal Judge Gulin’s decision and the decision became final on January 7, 2019.

b. Appeal No. 1-8415573880

On June 4, 2019, ALJ Jenifer Soulikias issued a decision in Appeal No. 1-8415573880 on claims related to the months of September, October, and November 2018 finding that coverage was appropriate for Mrs. Piekanski. Among other findings, Judge Soulikias found that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. *See* Pistorino Decl. ¶ 15, Ex. L at 9 (“Beneficiary established by a preponderance of the evidence that the electrical stimulation device (code E0766) for TTFT at issue is medically reasonable and necessary and meets the requirements for Medicare coverage.”). Thus, Judge Soulikias ordered coverage of Mrs. Piekanski’s claims. The Secretary chose not to participate in the hearing conducted by Judge Soulikias or to submit briefs. The Secretary did not appeal Judge Soulikias’ decision and the decision became final on August 4, 2019.

c. Appeal No. 1-8637781229

On September 13, 2019, ALJ Ryan Glaze issued a decision in Appeal No. 1-8637781229 on claims related to the months of June, July, and August 2018 finding that coverage was appropriate for Mrs. Piekanski. Among other findings, Judge Glaze found: 1) that Mrs. Piekanski’s GBM was “newly diagnosed” (as opposed to “recurrent”); and 2) that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. *See* Pistorino Decl. ¶ 16, Ex. M at 3 (“... the beneficiary’s GBM can be considered newly diagnosed ...”); 5

(“Therefore, I find that Medicare Part B covers the Optune TTFT (E0766) provided to the beneficiary on June 14, July 14, and August 14, 2018.”). Thus, Judge Glaze ordered coverage of Mrs. Piekanski’s claims. The Secretary chose not to participate in the hearing conducted by Judge Glaze or to submit briefs. The Secretary did not appeal Judge Glaze’s decision and the decision became final on November 13, 2019.

2. The Decision At Issue In This Case

On January 18, 2019, ALJ Glaze issued a decision in Appeal No. 1-8071086400 related to claims for coverage for the months of December 2017 through February 2018. There, contrary to the decisions issued above, Judge Glaze held that Mrs. Piekanski was not entitled to coverage. *See* Pistorino Decl. ¶ 13, Ex. J. For example, contrary the decision issued in September 2019, e.g., Judge Glaze held that Mrs. Piekanski’s GBM was considered “recurrent” rather than “newly diagnosed.” Again, contrary to the decisions listed above, Judge Glaze held that TTFT was not medically reasonable and necessary for Ms. Piekanski and not covered by Medicare.

Mrs. Piekanski timely appealed. In particular, Mrs. Piekanski noted the prior decisions from ALJs Gulin, Glaze, and Soulikias finding coverage appropriate. As a result, Mrs. Piekanski argued that the Secretary was collaterally estopped from re-litigating that issue.

When the Secretary did not issue a decision with the 90-day time frame provided by 42 U.S.C. § 1395ff(d)(2)(A), pursuant to 42 C.F.R. § 405.1132, Mrs. Piekanski filed a notice of escalation on November 15, 2019. When no response was received within the 5-day time limit of 42 C.F.R. § 405.1132(a)(1), ALJ Glaze’ decision became the final decision of the Secretary and Mrs. Piekanski timely filed this suit.

F. Facts Specific to Mr. Banks

Mr. Banks is a 74-year old, software designer, father of three (3) and grandfather to five (5). Mr. Banks has a PhD in Mechanical Engineering from MIT and was employed in the

aerospace business working on projects for NASA. Along with his wife of more than fifty (50) years (Betty), Mr. Banks currently lives in Madison, Alabama – just outside of Huntsville. In his free time, Mr. Banks performs missionary work (including translating the Bible into indigenous languages).

Mr. Banks was diagnosed with GBM in 2009 and, after surgery and chemo-radiation, Mr. Banks began using the Optune device in December 2013.

1. Favorable Decisions That Have Become Final

Appeal No. 1-8498071113

Appeal No. 1-8428973391

Appeal No. 1-8501252025

On June 6, 2019, ALJ Jeffrey Gulin issued decisions in Appeal Nos. 1-8498071113, 1-8428973391, and 1-8501252025 on claims related to the months of February and May-December 2018 finding that coverage was appropriate for Mr. Banks. Among other findings, Judge Gulin found that TTFT treatment was medically reasonable and necessary for Mr. Banks and a covered Medicare benefit. *See, e.g.*, Pistorino Decl. ¶ 18, Ex. O at 7 (“The service is medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. [Mr. Banks] is entitled to Medicare coverage”). Thus, Judge Gulin ordered coverage of Mr. Bank’s claims. The Secretary chose not to participate in the hearing conducted by Judge Gulin or to submit briefs. The Secretary did not appeal Judge Gulin’s decision and the decision became final on August 6, 2019.

2. The Decision At Issue In This Case

On June 3, 2019, ALJ Bruce Kelton issued a decision in Appeal No. 1-813649506 on claims related to the months of January, March and April of 2018. Contrary to the decisions by Judge Gulin, Judge Kelton held that TTFT was not medically reasonable and necessary for Mr.

Banks and was not a covered benefit. *See* Pistorino Decl. ¶ 17, Ex. N at 12 (“... not medically reasonable and necessary. Payment is therefore not allowed by Medicare.”).

Mr. Banks timely appealed. In particular, Mr. Banks noted the prior decisions from ALJ Gulin finding coverage appropriate. As a result, Mr. Banks argued that the Secretary was collaterally estopped from re-litigating that issue.

When the Secretary did not issue a decision with the 90-day time frame provided by 42 U.S.C. § 1395ff(d)(2)(A), pursuant to 42 C.F.R. § 405.1132, Mr. Banks filed a notice of escalation on November 15, 2019 again arguing that the Secretary was collaterally estopped from denying coverage. When no response was received within the 5-day time limit of 42 C.F.R. § 405.1132(a)(1), ALJ Kelton’s decision became the final decision of the Secretary and Mr. Banks timely filed this suit.

III. DISCUSSION

As a result of the prior decisions finding TTFT “medically reasonable and necessary” and a covered benefit for Messrs. Wilmoth and Banks and Ms. Piekanski, the Secretary is collaterally estopped from issuing denials on the same grounds that were rejected by prior decisions. Further, in light of the prior decisions finding coverage and the absence of a change in the facts/circumstances, the Secretary’s decisions denying coverage are arbitrary and capricious and should be reversed. Under either or both rationales, pursuant to 42 U.S.C. § 405(g)(fourth sentence), the Court should reverse the Secretary’s denials, order coverage, and remand these cases with instruction to effectuate the decision.

A. Collateral Estoppel

Collateral estoppel should bar the Secretary from relitigating the issue of coverage for Plaintiffs, the decisions at issue should be reversed, and coverage ordered.

1. The Secretary Is Collaterally Estopped From Asserting That TTFT Is Not A Medicare Covered Benefit For Messrs. Wilmoth and Banks and Mrs. Piekanski

As noted above, in each of the prior, final decisions, the issue of whether TTFT was a Medicare covered benefit/was “medically reasonable and necessary” was decided in Plaintiffs’ favor. Nevertheless, in Appeal No. 1-8363484331 (for Mr. Wilmoth), Appeal No. 1-8071086400 (for Mrs. Piekanski), and Appeal No. 1-813649506 (for Mr. Banks) (collectively, “the decisions at issue”), the ALJs concluded that TTFT was not a covered benefit/“medically reasonable and necessary.” The Secretary is collaterally estopped from re-litigating the issue of whether TTFT is a covered benefit/is “medically reasonable and necessary” for Messrs. Wilmoth and Banks and Mrs. Piekanski.

a. The Issue Was Actually Litigated in the Prior Proceedings

As detailed above, the issue of whether TTFT was a Medicare-covered benefit/was “medically reasonable and necessary” for each of the Plaintiffs was actually litigated in each of the prior favorable cases. Of course, whether a device/procedure is “medically reasonable and necessary” is the basis on which it is decided whether the device/procedure is a covered benefit. Thus, in each case, by appealing initial denials and seeking an ALJ hearing, that issue was necessarily being litigated.

For example, in Appeal No. 1-7835229465 (for Mrs. Piekanski) ALJ Gulin described one of the issues to be decided as: “Whether the service provided are medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act (“Act”) and covered under Medicare.” *See* Pistorino Decl. ¶ 11, Ex. H at 2. In each of the decisions giving rise to collateral estoppel, the issue of whether TTFT was “medically reasonable and necessary” and a covered benefit was actually litigated.

**b. The Issue Was Actually and Necessarily Determined
By a Court of Competent Jurisdiction**

In each of the prior cases, the ALJs actually determined that TTFT was “medically reasonable and necessary” and a covered benefit. Further, they must necessarily have done so because coverage (predicated on the fact that the device/procedure is “medically reasonable and necessary”) was the thing being litigated/the relief sought.

For example, in Appeal No. 1-8236683474 (for Mr. Wilmoth) ALJ Henningfeld concluded: “[TTFT] does satisfy the applicable Medicare coverage criteria. [TTFT] was reasonable and necessary. It is therefore covered under Medicare Part B.” In each of the decisions giving rise to collateral estoppel, the ALJ determined that TTFT was a Medicare covered benefit (because it was “medically reasonable and necessary” and satisfied Medicare coverage criteria).

It is beyond peradventure that the ALJs are courts of competent jurisdiction. Pursuant to Congress’ command to provide “hearings” (42 U.S.C. § 405(g)), these are the primary courts established by the Secretary for litigating the issue of coverage.

c. The Prior Decisions Are Final Decisions

As noted above, Messrs. Wilmoth and Banks and Mrs. Piekanski each received favorable decisions from ALJs covering multiple appeals. Pursuant to 42 C.F.R. § 405.1048(a), ALJ decisions are “binding on all parties” unless timely appealed to the Council (or other exceptions not relevant here). Timely appeals to the Council must be filed within 60 days. *See* 42 C.F.R. § 405.1110(a)/(b)(2).

No appeal (much less a timely one) to the ALJs’ decisions was filed. Thus, each decision is a final decision of the Secretary. *See* 70 Fed.Reg. 36386-7 (June 23, 2005) (“The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]”). *See also Smith v. Berryhill*, 139 S.Ct.

1765, 1775-6 (2019) (under APA, action is “final” if it: 1) marks the consummation of the agency’s decision making process; and 2) is one by which rights have been determined or from which legal consequences will flow).

In some cases, the prior final decisions giving rise to estoppel occurred after the ALJ’s decisions against which estoppel is asserted. For example, Mrs. Piekanski asserts that the decision in Appeal No. 1-8071086400 issued on January 18, 2019 is collaterally estopped by the final decision in Appeal No. 1-8415573880 issued on June 4, 2019. As noted above, this is so because the first decision to become final can collaterally estop an earlier issued (but not final) decision. *See Kline*, 260 U.S. at 230; *Adkins*, 779 F.3d at 484. Thus, the result in an earlier issued, but non-final, case may be controlled by a later issued, but final, case. In any event, Mr. Wilmoth and Mrs. Piekanski have at least one final decision issued before the decisions at issue in this case. Accordingly, the Court need not even consider the issue in their cases.

d. Full and Fair Opportunity to Litigate

Some descriptions of collateral estoppel include an inquiry as to whether there was a “full and fair opportunity to litigate” the issue on which estoppel is asserted. *See, e.g., Oyeniran v. Holder*, 672 F.3d 800, 806 (9th Cir. 2012). In the interests of completeness, Plaintiffs note that the Secretary had a full and fair opportunity to litigate the issue of whether TTFT was a covered benefit/was reasonable and necessary for Plaintiffs. At any time, the Secretary could have appeared in the ALJ proceedings to contest or put forward the Secretary’s views on that issue. Instead, in each instance, the Secretary chose not to participate in the ALJ hearing process and further chose not to appeal. Thus, the Secretary had a full and fair opportunity to litigate the issues.

e. The Application of Collateral Estoppel Will Not Work a Basic Unfairness

There is simply no reason to believe that applying collateral estoppel against the Secretary will be unfair to the Secretary. Indeed, *not* applying collateral estoppel would be unfair to Plaintiffs. Plaintiffs, Medicare beneficiaries, have already sustained the burden of litigating the same position multiple times and should not be forced to bear the expense and uncertainty of repeatedly litigating the same issue. This is particularly true in this case where Plaintiffs are suffering from an extremely lethal form of cancer and are seeking coverage of a life-extending treatment.

2. The Decisions At Issue Should Be Reversed and Coverage Ordered

Given the application of collateral estoppel to the issue of whether TTFT is a covered benefit/is “medically reasonable and necessary” for Plaintiffs, the decisions at issue should be reversed. Each of the decisions denying coverage was premised solely on the conclusion that TTFT was not “medically reasonable and necessary” for each of the Plaintiffs. That is, there was no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, then there is no reason that coverage can/should be denied.

Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court can modify or reverse the Secretary’s decisions “with or without remanding the cause for a rehearing.” If the Secretary is collaterally estopped from denying coverage to Plaintiffs in Appeal No. 1-8363484331 (for Mr. Wilmoth), Appeal No. 1-8071086400 (for Mrs. Piekanski), and Appeal No. 1-813649506 (for Mr. Banks), then there is no need or reason for further review by the Secretary and coverage should be ordered.

3. The Secretary's Arguments Regarding Collateral Estoppel Lack Merit

Plaintiffs asserted collateral estoppel during the proceedings below both before the ALJs (where the timing permitted) and before the Council. In one instance, while acknowledging prior favorable decisions for the same beneficiary on the same issue, the ALJ simply did not discuss collateral estoppel before reaching a contrary conclusion. *See* Pistorino Decl. ¶ 5, Ex. B at 4; Pistorino Decl. ¶ 7, Ex. D at 6. In another instance, the judge did not acknowledge the prior favorable decision. *See* Pistorino Decl. ¶ 12, Ex. I; Pistorino Decl. ¶ 13, Ex. J.⁵

At the Council, Plaintiffs again asserted collateral estoppel. *See* Pistorino Decl. ¶ 8, Ex. E at 5; Pistorino Decl. ¶ 14, Ex. K; Pistorino Decl. ¶ 19, Ex. P. Only in Mr. Wilmoth's appeal did the MAC address the issue.⁶ There, the MAC stated:

Finally, the beneficiary argues that the ALJ was estopped from denying coverage based on two prior ALJ rulings finding that Medicare coverage of TTFT provided to the beneficiary on different dates of service was reasonable and necessary. However, ALJ decisions do not have precedential effect. Moreover, it is generally the role of the Council, which like the ALJ conducts a *de novo* review of the entire administrative record, to issue final decisions on behalf of the Secretary. Thus, issue preclusion is not applicable here.

(internal citations omitted).

It is elemental that “precedence” and “collateral estoppel” are distinct legal concepts. A “precedential” decision is controlling on all subsequent decisions of inferior tribunals as against all parties. By contrast, “collateral estoppel” only affects the rights of the parties to the particular decision on which collateral estoppel is based. Further, collateral estoppel may bind tribunals superior to the issuing one. Because of the difference between “precedence” and “collateral

⁵ In the final instance (Banks), the decision(s) on which preclusion is based issued after the ALJ's hearing and decision but before the decision became final.

⁶ In the cases of Mrs. Piekanski and Mr. Banks, the MAC did not issue a decision within the time frame required by a request for escalation or before suit was filed.

estoppel”, it is very common for prior, non-precedential decisions to collaterally estop a party from re-litigating an issue. Thus, the Secretary’s statements regarding “precedence” simply miss the mark.

What is relevant is whether all the elements of collateral estoppel are present. Given that they are, the Secretary is estopped from re-litigating the issues decided in the prior cases. As noted by the Supreme Court in *Astoria*, it is presumed that Congress legislates against the backdrop of the common law, including collateral estoppel. *Astoria*, 501 U.S. at 108. Further, the Secretary may not simply ignore commands of the Supreme Court that the Secretary finds inconvenient.

B. The Secretary’s Decisions Are Arbitrary and Capricious

As noted above, absent a legitimate reason, the treatment of functionally indistinguishable cases must be consistent or an agency is acting arbitrarily and capriciously. *Independent Petroleum*, 92 F.3d at 1258. Here, no legitimate reason was offered (or exists) for the differing decisions. For example, ALJs determined that TTFT was “medically reasonable and necessary” (and a covered benefit) for Mr. Wilmoth for the months of October 2017-March 2018 and July 2018-March 2019. For some unexplained reason, the exact same treatment, to the exact same person, suffering from the exact same condition, was not “medically reasonable and necessary” during the months of April, May, and June 2018.

Likewise, the decisions concluding that TTFT was not “medically reasonable and necessary” (and therefore not covered) for both Mrs. Piekanski and Mr. Banks are not consistent with the prior decisions and there is no legitimate reason for the difference.

IV. CONCLUSION

For the reasons set forth above, the Court should issue an Order finding that the Secretary is collaterally estopped from relitigating the issue of TTFT coverage for Plaintiffs. In addition to

or in the alternative, the Court should issue an Order finding that the Secretary's decisions denying coverage are arbitrary and capricious. Under either or both rationales, the Court should issue an Order directing the Secretary to provide coverage for the claims at issue in Appeal No. 1-8363484331 (for Mr. Wilmoth), Appeal No. 1-8071086400 (for Mrs. Piekanski), and Appeal No. 1-8136495060 (for Mr. Banks).

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Respectfully submitted,

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